

Contents: Evaluation of Seller Quality Assurance (QA) Programs

Effective Date: October 2000

Point of Contact: Quality Program Office

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Evaluation of Seller QA Program Flowchart

Forms

Seller QA Program History Form
Seller Quality Evaluation Form
Third-Party Evaluation of Seller QA Program Form

Training Requirements and Reporting Obligations

This subject area does not contain training requirements.

This subject area may or may not contain reporting obligations. See the subject area until obligations are listed here.

References

Graded Approach for Quality Requirements Subject Area

Purchase Requisition Review for Quality-related Requirements Subject Area

Standards of Performance

All staff and users shall identify, evaluate, and control hazards in order to ensure that work is conducted safely and in a manner that protects the environment and the public.

All staff shall clearly and completely specify appropriate requirements for purchased goods and services

consistent with project needs.

All scientific and professional staff shall identify and control items and material affecting scientific results.

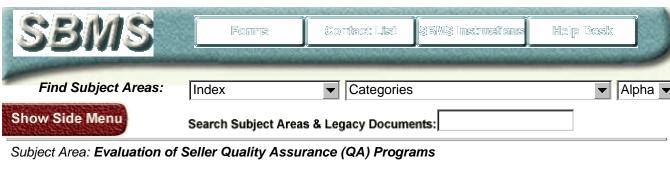
Management System

This subject area belongs to the **Quality Management** management system.

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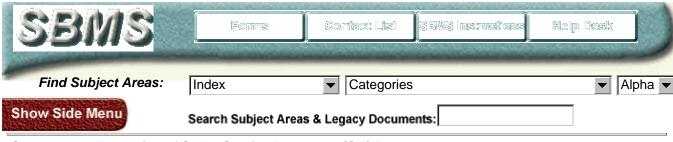
This subject area defines a process based upon a graded approach, for evaluating a prospective seller's Quality Assurance (QA) program by Brookhaven National Laboratory (BNL).

This process includes information on how to

- choose the appropriate evaluation method(s),
- document the results of the evaluation, and
- proceed when an unacceptable seller's QA program is identified.

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1. Determining When and How to Evaluate a Seller's QA Program

Effective Date: October 2000

Point of Contact: Quality Program Office

Applicability

This information applies to the responsible individual or designee, Quality Representative (QR), and personnel from the Procurement & Property Management Division (PPM), who prepare, review, or approve purchase requisitions. This involves all procurements of items or services for Brookhaven National Laboratory (BNL) projects.

Required Procedure

The quality classification of High (A1), Moderate (A2), Low (A3), or Negligible (A4) is selected and assigned to a purchase requisition (REQ) in accordance with the <u>Graded Approach for Quality Requirements</u> and <u>Purchase Requisition Review for Quality-related Requirements</u> Subject Areas. These classifications are equivalent to the ESH&Q Risk Levels of Critical (A1), Major (A2), Minor (A3), or Negligible (A4).

Before an evaluation is conducted, PPM determines if the seller (such as a manufacturer or distributor) has any outstanding discrepancies that should be added to the seller's QA program evaluation.

Note: PPM also identifies any sellers that should be removed from consideration.

Technical criteria can range from very simple (e.g., a brand name or equal for a commercial item) to very complex (e.g., a technical approach to the development of a prototype membrane with specified chemical differentiation properties). For a seller's QA program evaluation, the selection of an evaluation strategy is determined before a solicitation is issued.

The responsible individual or designee proceeds as follows:

| Determine if a seller's QA program evaluation is required. Refer to the Evaluation of Seller QA Program Flowchart for an overview of this subject area.

For items classified as ESH&Q Risk Levels A1 or A2, a seller's QA program evaluation is required unless

• the seller has had a documented QA program evaluation accepted by BNL within the last 3 years (for the same or similar product) or

• the responsible individual or designee has justification to waive an evaluation for items that are either sole source or made to manufacturer's specifications (off-the-shelf).

For items classified as ESH&Q Risk Levels A3 or A4, an evaluation is optional.

Note: For further assistance, contact your QR or the Quality Program Office.

Note: Because BNL Divisions/Departments fall under the Laboratory-wide Quality Assurance program for their activities, a seller evaluation is not required when products/services are provided internally.

Step 2

Conduct the evaluation by selecting the appropriate method as described below:

- Seller history used to identify similar items procured. The responsible individual or designee provides documentation via the <u>Seller QA Program History Form</u> or equivalent.
- Desk survey the seller's facility and quality assurance program are surveyed by using the seller's QA Manual, if available, or by conducting discussions with the seller's technical personnel. The seller provides documentation via the <u>Seller Quality Evaluation Form</u> or equivalent. This form may be included in the request for quotation package and completed by the seller.
- Third-party evaluation of seller QA program evaluations of an assessment/survey are
 performed by another laboratory, or company, such as International Standards
 Organization (ISO) 9000 Certification. The Suppliers Quality Information Group (SQIG)
 Database is available through the BNL Quality Program Office and may be used for this
 purpose. If the Seller's Quality System meets the applicable ISO 9000 Certification,
 American Society of Mechanical Engineers (ASME) Specifications, SQIG, or other suitable
 standards of qualification, they may meet the requirements of a QA program evaluation.
 The responsible individual or designee provides documentation via the Third-Party
 Evaluation of Seller QA Program Form or equivalent.
- On-site visit and survey method a walk-through of the seller's facility and implementation
 of the quality assurance program using the <u>Seller Quality Evaluation Form</u> may be
 conducted to confirm that the vendor meets the requirements as stated in the purchase
 requisition. Specific requirements from the requisition may be added to the Seller Quality
 Evaluation Form or equivalent.

Step 3

Document the results of the seller's QA program evaluation.

Note: Documentation is required for A1 and A2 procurements.

If a seller's QA program evaluation has no deficiencies, the PPM processes the REQ.

If deficiencies are found, inform the seller of the finding(s). If the seller

- corrects the finding(s) in a reasonable time frame and demonstrates the corrective action (s), PPM processes the REQ, or
- does not correct the finding(s), determine the appropriate course of action.

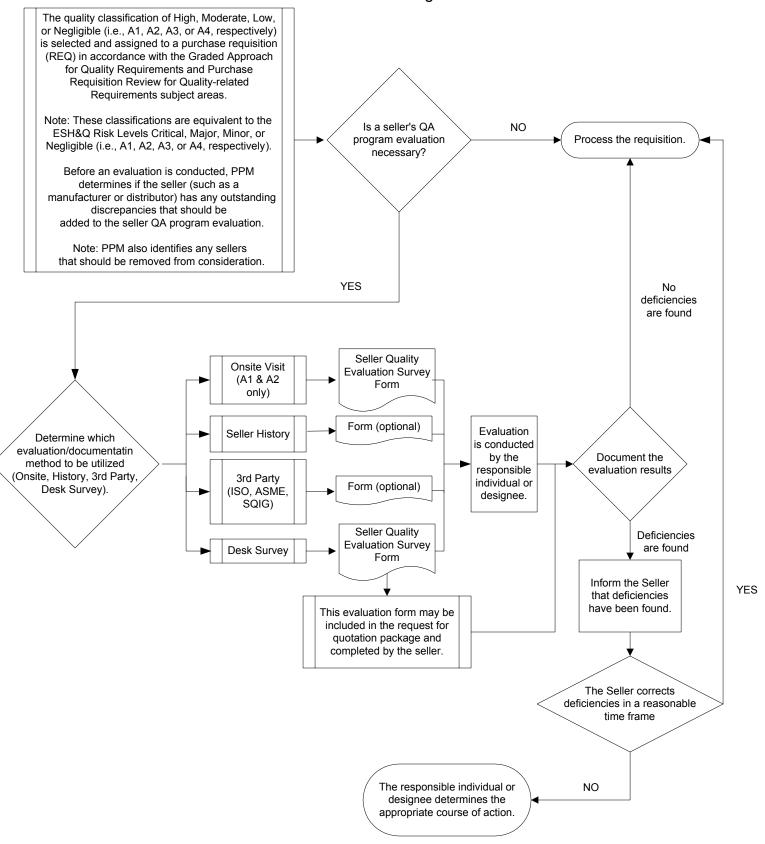
References

Graded Approach for Quality Requirements Subject Area

Purchase Requisition Review for Quality-related Requirements Subject Area

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Seller QA Program History

Company Name:
Address:
Contact, Title:
History Review Date:
Performed By:
Commodity:
Commodity Description:
Commodity Code:
Quality Program:
Quality Records Reviewed:
Brookhaven National Laboratory Requirements:
QA Program Evaluation Summary:
Auditor:

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Seller Quality Evaluation Form

Desk Survey (completed by BNL):

Desk Survey (completed by Seller):

On-site Visit and Survey (completed by BNL):

Company Name:			
Company Address:			
Telephone Number:			
Prepared by:		Title:	
Names of Officers, Owners			
President:			
Vice President:			
Division of subsidiary of:			
Number of Employees:	Personnel in QA:	Insp. & Test:	Production:
Building Quantity:	Building Square Footage:	Age	e of Building:
Person to be contacted con	cerning proposals and cor	ntracts:	
<u>Name</u>		<u>Title</u>	

FOR INTERNAL USE ONLY				
Please give an overall in	mpression of seller's qualification and capability.			
S				
_				
RNI Representative:	Date:			
BNL Representative:	Date.			

1.0	QUAL	ITY SYSTEMS						
	1.1	Is there a writ	ten QA Plan	or QA	Program?	YES	NO	N/A
	1.2	Is the QA Pro	gram approv	ved to a	ny standar	ds? YES	NO	N/A
		Please attach	letters of ap	oproval	and/or cert	ificates.		
	1.3	Who is respor	nsible for QA	A in the	plant?			
	1.4	Are procurem	ents, proces	sses, ar	nd inspectio	n functior	ns audited by y	our QA
		organization?		YES	NO	1	N/A	
	1.4	Are process c	ontrol and ir	nspectio	on instrume	nts period	dically calibrate	ed?
		YES	NO	N/A	How often	are they	calibrated?	
	1.5	Are calibration	n records av	ailable	for gages a	nd instrur	ments? YES	NO N/A
	1.6	Are these cali	brations trad	ceable t	to the Natio	nal Institu	te of Standard	s and
		Technology (N	NIST)?	YES	NO N/A	١		
	1.7	Are gage bloc	ks or secon	dary sta	andards ava	ailable to i	inspectors? YE	ES NO N/A
	1.8	Are your supp	oliers' test re	ports a	nd records	checked f	or acceptabilit	y?
		YES NO	N/A					
	1.9	Are records ke	ept showing	the acc	ceptance, re	ejection, c	or disposal of n	naterial?
		YES NO	N/A					
	1.10	Are there any	certification	s unde	r any other	licensing	or qualification	n program
		(AWS-ASME	Welder Qua	alificatio	ns, Nondes	tructive T	est Society)?_	
	1.11			-			er complaints?	?
		YES	NO	How	do you resp	ond to the	em?	

2.0 **CONTROL OF PURCHASED ITEMS**

3.0

4.0

2.1	Do you qualify suppliers and subcontractors?	YES	NO	N/A	
2.2	Is a quality history maintained for each suppli	er?	YES	NO	N/A
2.3	Are incoming materials inspected? YES	NO	N/A		
2.4	Are written inspection procedures used?	YES	NO	N/A	
2.5	Do you have a system for identifying and labe	eling ma	terials?	•	
	YES NO N/A				
2.6	Is defective material identified and segregate	d?	YES	NO	N/A
2.7	Is reworked material reinspected? YES	NO	N/A		
2.8	Is space for storage and control of materials a	adequat	e? YES	NO S	N/A
2.9	Are records kept showing the acceptance, rej	ection,	or dispo	sal of	material?
	YES NO N/A				
2.10	Do you have a system for disposition of nonc	onformiı	ng mate	erials?	YES NO N/A
2.11	Is there a system for supplier corrective action	n?	YES	NO	N/A
2.12	Are raw materials controlled and are material	analyse	es perio	dically	verified?
	YES NO N/A				
PRO	CESS CONTROL				
3.1	Do you have a process inspection function?	YES	NO	N/A	
	Who does the inspection?				
3.2	Do you have a system for reviewing new production	cess spe	ecificati	ons an	d inspection
	instructions? YES NO N/A				
3.3	Do you have an in-process identification and	recordir	ng syste	m, suc	ch as routing
	cards? YES NO N/A				
<u>ENGI</u>	NEERING CAPABILITY				
4.1	Do you have capability for producing shop dra	awings a	and too	ling de	sign?
	YES NO N/A				
4.2	Are customer specifications interpreted into s	hop spe	cification	ons an	d inspection
	instructions? YES NO N/A				
4.3	Are drawing and specifications prepared for purchase orders and				
	subcontractors? YES NO N/A				

	YES NO N/A
4.5	Are revisions reviewed for conformity to customer's specifications?
	YES NO N/A
4.6	Are revisions reviewed for quality requirements before submission for customer
	approval? YES NO N/A
FINA	AL INSPECTION
5.1	Is there a final inspection before delivery to the customer? Is this inspection
	documented on a traveler or other final inspection paperwork? YES NO N/A
5.2	Does the organization have the final inspection function separate from the
	production function? YES NO N/A
5.3	Are written inspection instructions, product specifications, and drawings
	available? YES NO N/A
	How are these reviewed and kept up-to-date?
<u>Non</u>	-Conforming Material
<u>Non</u> 6.1	-Conforming Material Is there a Material Review Board (MRB) with the responsibility to review &
'	
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6.1 6.2 6.3	Is there a Material Review Board (MRB) with the responsibility to review & disposition nonconforming material? YES NO N/A Is material awaiting review adequately segregated and identified? YES NO N/A Is there a designated locked area for staging material waiting for disposition by
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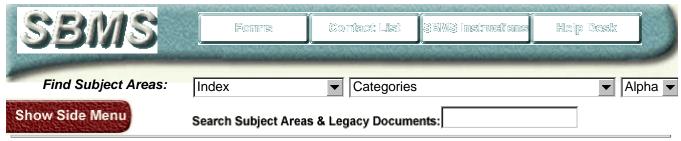
Are drawings and specifications kept up-to-date and controlled?

4.4

Third-Party Evaluation of Seller QA Program

Type of	Third-Party Evaluation:
A)	International Standards Organization (ISO) 9001
	9003
B)	American Standards of Mechanical Engineers (ASME)
C)	Supplier Quality Information Group (SQIG) \Box
	Criteria:
D)	Other Source (list name):
	Date of evaluation (m/d/yy):
	Contact individual (for future reference):
	Contact phone:
	Current certificates on file (Y/N):

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Definitions: Evaluation of Seller Quality Assurance (QA) Programs

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Point of Contact: Quality Program Office

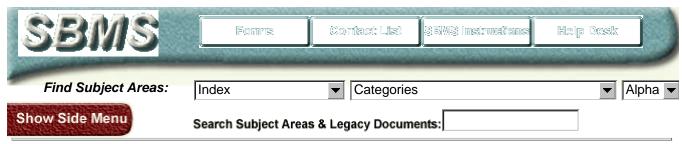
Term	Definition		
buyer	Brookhaven Science Associates operating Brookhaven National Laboratory acting by and through its Division of Contracts and Procurement issuing the purchase order.		
graded approach	A process for determining that the appropriate level of analysis, controls, documentation, and actions necessary are commensurate with an item's or activity's potential to		
	 create an environmental, safety, or health hazard; incur a monetary loss due to damage, or to repair/rework/scrap costs; reduce the availability of a facility or equipment; adversely affect the program objective or degrade data quality; or unfavorably impact the public's perception of the BNL/DOE mission. 		
off-the-shelf item	A product manufactured by a seller for inventory, rather than a specific order; or an item procured from an independent distributor.		
	Note: Some catalog items are "made-to-order" and are not considered to be off-the-shelf items.		
purchase requisition (REQ)	A procurement document that specifies the requirements for an item or service to be purchased.		
Quality Assurance (QA) program	A written description of the responsibilities for, and manner in which the quality assurance functions are planned and carried out to ensure the achievement of programmatic objectives.		
quality classification	An indicator using a weighted scale that is used once the ES&H and programmatic risks have been evaluated, e.g., A1 (Critical), A2 (Major), A3 (Minor), and A4 (Negligible).		
Quality Representative (QR)	The technical representative assigned to coordinate, assist, and monitor the implementation of quality assurance activities within a department/division.		
responsible individual	The individual within a department or division responsible for selecting and applying quality-related items or activities to be incorporated in a purchase requisition.		
seller	The legal entity which is the contracting party with the buyer with respect to the purchase order(s). The seller includes, but is not limited to, manufacturers or distributers.		

Supplier Quality Information Group (SQIG) Supplier Quality Information Group (SQIG) is a group of U.S. Department of Energy (DOE) contractors, responding to the concerns of customers and stakeholders who developed a strategy to minimize duplicate contractor evaluations of suppliers. SQIG has developed a forum for sharing supplier evaluation data, lowering costs, and exchanging information and ideas that promote excellence in all aspects of supplier quality activities.

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Revision History: Evaluation of Seller Quality Assurance (QA) Programs

Point of Contact: Quality Program Office

Revision History of this Subject Area

Date	Description	Management System
October 2000	This subject area provides a methodology for selecting and conducting an evaluation of a prospective seller's QA program. The quality-related requirements selected are based upon the graded approach.	Quality Management

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